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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,635	02/12/2004	John J. Rossi	1954-418	1769

6449 7590 06/28/2005

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EXAMINER

BOWMAN, AMY HUDSON

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/776,635	Applicant(s) ROSSI ET AL.	
	Examiner Amy H. Bowman	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/12/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 4, 6-21 and 23-25, drawn to a method for methylating a gene of interest, wherein the gene is an infectious agent gene or a viral infectious agent gene in a mammalian cell, wherein the target sequence is located in a promoter region of the gene of interest, and wherein the method causes inactivation of the gene of interest, classified in class 514, subclass 44.
- II. Claims 1, 2, 4, 6-21, 23, 24 and 26, drawn to a method for methylating a gene of interest, wherein the gene is an infectious agent gene or a viral infectious agent gene in a mammalian cell, wherein the target sequence is located in a promoter region of the gene of interest, and wherein the method causes activation of the gene of interest, classified in class 514, subclass 44.
- III. Claims 1, 2, 4, 6-8, 11-22 and 23-25, drawn to a method for methylating a gene of interest, wherein the gene is a RASSF1 gene, wherein the target sequence is located in a promoter region of the gene of interest, and wherein the method causes inactivation of the gene of interest, classified in class 514, subclass 44.
- IV. Claims 1, 2, 4, 6-8, 11-22, 23, 24 and 26, drawn to a method for methylating a gene of interest, wherein the gene is a RASSF1 gene,

wherein the target sequence is located in a promoter region of the gene of interest, and wherein the method causes activation of the gene of interest, classified in class 514, subclass 44.

- V. Claims 1, 3, 5-21 and 23-25, drawn to a method for methylating a gene of interest, wherein the gene is an infectious agent gene or a viral infectious agent gene in a mammalian cell, wherein the target sequence is located in a coding region of the gene of interest, and wherein the method causes inactivation of the gene of interest, classified in class 514, subclass 44.
- VI. Claims 1, 3, 5-21, 23, 24 and 26, drawn to a method for methylating a gene of interest, wherein the gene is an infectious agent gene or a viral infectious agent gene in a mammalian cell, wherein the target sequence is located in a coding region of the gene of interest, and wherein the method causes activation of the gene of interest, classified in class 514, subclass 44.
- VII. Claims 1, 3, 5-8, 11-22 and 23-25, drawn to a method for methylating a gene of interest, wherein the gene is a RASSF1 gene, wherein the target sequence is located in a coding region of the gene of interest, and wherein the method causes inactivation of the gene of interest, classified in class 514, subclass 44.
- VIII. Claims 1, 3, 5-8, 11-22, 23, 24 and 26, drawn to a method for methylating a gene of interest, wherein the gene is a RASSF1 gene, wherein the target sequence is located in a coding region of the gene of interest, and

wherein the method causes activation of the gene of interest, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

The invention of group I is unrelated to the invention of group II. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group I is drawn to a method of inactivating a gene of interest, whereas group II is drawn to activating a gene of interest. The two groups have opposite effects, resulting in the need for a separate examination. A search for one of these inventions would not necessarily return art against the other invention, due to the separate outcomes of each method. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group I is unrelated to the invention of group III. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group I is drawn to a method of methylating an infectious agent gene or a viral infectious agent gene, whereas group III is drawn to a method of methylating a RASSF1 gene. Each of the different target genes have separate nucleotide sequences containing no common core. A search against

one of the inventions would not necessarily return art for the other invention due to the separate and distinct target genes. A search for one of these inventions would not necessarily return art against the other invention, due to the difference in genes being targeted. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group I is unrelated to the invention of group IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group I is drawn to a method of methylating an infectious agent gene or a viral infectious agent gene, whereas group IV is drawn to a method of methylating a RASSF1 gene. Each of the different target genes have separate nucleotide sequences containing no common core. A search against one of the inventions would not necessarily return art for the other invention due to the separate and distinct target genes. A search for one of these inventions would not necessarily return art against the other invention, due to the difference in genes being targeted. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group I is unrelated to the invention of group V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as

capable of use together and have different effects. Group I is drawn to a method of methylating a gene comprising exposing a cell to an siRNA which is specific for a target sequence in a promoter region of the gene, whereas group IV is drawn to a method of methylating a gene comprising exposing a cell to an siRNA which is specific for a target sequence in a coding region of the gene. The sequence of the promoter region and the sequence of the coding region do not contain a common structural core. The siRNA molecules targeted to such sequences would each be separate and unique. A search against one of the inventions would not necessarily return art for the other invention due to the separate and distinct target regions. A search for one of these inventions would not necessarily return art against the other invention. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group I is unrelated to the invention of group VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group I is drawn to a method of methylating a gene comprising exposing a cell to an siRNA which is specific for a target sequence in a promoter region of the gene and inactivating a gene of interest, whereas group VI is drawn to a method of methylating a gene comprising exposing a cell to an siRNA which is specific for a target sequence in a coding region of the gene and activating a gene of interest. The two groups have opposite effects, as well as targeting different regions. The sequence of the promoter region and the sequence of the coding

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region do not contain a common structural core. The siNA molecules targeted to such sequences would each be separate and unique, resulting in the need for a separate examination. A search for one of these inventions would not necessarily return art against the other invention. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group I is unrelated to the invention of group VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group I is drawn to a method of methylating an infectious agent gene or a viral infectious agent gene comprising exposing a cell to an siRNA which is specific for a target sequence in a promoter region of the gene, whereas group VII is drawn to a method of methylating a RASSF1 gene comprising exposing a cell to an siRNA which is specific for a target sequence in a coding region of the gene. Not only are the two groups targeted to separate and distinct genes, but they are also targeted to different regions on the gene of interest. Each of the different target genes, as well as regions within those genes, have separate nucleotide sequences containing no common core. The siNA molecules targeted to such sequences would each be separate and unique, resulting in the need for a separate examination. A search for one of these inventions would not necessarily return art against the other invention. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group I is unrelated to the invention of group VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group I is drawn to a method of methylating an infectious agent gene or a viral infectious agent gene comprising exposing a cell to an siRNA which is specific for a target sequence in a promoter region of the gene and inactivating the gene, whereas group VIII is drawn to a method of methylating a RASSF1 gene comprising exposing a cell to an siRNA which is specific for a target sequence in a coding region of the gene and activating the gene. The two groups are targeted to separate and distinct genes, are targeted to different regions on the genes, and have different effects. Each of the different target genes, as well as regions within those genes, have separate nucleotide sequences containing no common core. The siRNA molecules targeted to such sequences would each be separate and unique, resulting in the need for a separate examination. Additionally, each of the groups have opposite outcomes, each requiring a separate examination. A search for one of these inventions would not necessarily return art against the other invention. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group II is unrelated to the invention of group III. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group II is drawn to a method of methylating an infectious agent gene or a viral infectious agent gene comprising exposing a cell to an siRNA which is specific for a target sequence and activating the gene of interest, whereas group III is drawn to a method of methylating a RASSF1 gene comprising exposing a cell to an siRNA which is specific for a target sequence and inactivating the gene of interest. Not only are the two groups targeted to separate and distinct genes, but they also have opposite effects. Each of the different target genes have separate nucleotide sequences containing no common core. The siRNA molecules targeted to such sequences would each be separate and unique, resulting in the need for a separate examination. A search for one of these inventions would not necessarily return art against the other invention. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group II is unrelated to the invention of group IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group II is drawn to a method of methylating an infectious agent gene or a viral infectious agent gene, whereas group IV is drawn to a method of methylating a RASSF1 gene. Each of the different target genes have separate nucleotide sequences containing no common core. A search against one of the inventions would not necessarily return art for the other invention due to the

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separate and distinct target genes. A search for one of these inventions would not necessarily return art against the other invention, due to the difference in genes being targeted. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group II is unrelated to the invention of group V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group II is drawn to a method of methylating a gene comprising exposing a cell to an siRNA which is specific for a target sequence in a promoter region of the gene and activating a gene of interest, whereas group V is drawn to a method of methylating a gene comprising exposing a cell to an siRNA which is specific for a target sequence in a coding region of the gene and inactivating a gene of interest. The two groups have opposite effects, as well as targeting different regions. The sequence of the promoter region and the sequence of the coding region do not contain a common structural core. The siNA molecules targeted to such sequences would each be separate and unique, resulting in the need for a separate examination. A search for one of these inventions would not necessarily return art against the other invention. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group II is unrelated to the invention of group VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and

they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group II is drawn to a method of methylating a gene comprising exposing a cell to an siRNA which is specific for a target sequence in a promoter region of the gene, whereas group VI is drawn to a method of methylating a gene comprising exposing a cell to an siRNA which is specific for a target sequence in a coding region of the gene. The sequence of the promoter region and the sequence of the coding region do not contain a common structural core. The siRNA molecules targeted to such sequences would each be separate and unique. A search against one of the inventions would not necessarily return art for the other invention due to the separate and distinct target regions. A search for one of these inventions would not necessarily return art against the other invention. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group II is unrelated to the invention of group VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group II is drawn to a method of methylating an infectious agent gene or a viral infectious agent gene comprising exposing a cell to an siRNA which is specific for a target sequence in a promoter region of the gene and activating the gene, whereas group VII is drawn to a method of methylating a RASSF1 gene comprising exposing a cell to an siRNA which is specific

for a target sequence in a coding region of the gene and inactivating the gene. The two groups are targeted to separate and distinct genes, are targeted to different regions on the genes, and have different effects. Each of the different target genes, as well as regions within those genes, have separate nucleotide sequences containing no common core. The siRNA molecules targeted to such sequences would each be separate and unique, resulting in the need for a separate examination. Additionally, each of the groups have opposite outcomes, each requiring a separate examination. A search for one of these inventions would not necessarily return art against the other invention. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group II is unrelated to the invention of group VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group II is drawn to a method of methylating an infectious agent gene or a viral infectious agent gene comprising exposing a cell to an siRNA which is specific for a target sequence in a promoter region of the gene, whereas group VIII is drawn to a method of methylating a RASSF1 gene comprising exposing a cell to an siRNA which is specific for a target sequence in a coding region of the gene. Not only are the two groups targeted to separate and distinct genes, but they are also targeted to different regions on the gene of interest. Each of the different target genes, as well as regions within those genes, have separate

nucleotide sequences containing no common core. The siNA molecules targeted to such sequences would each be separate and unique, resulting in the need for a separate examination. A search for one of these inventions would not necessarily return art against the other invention. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group III is unrelated to the invention of group IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group III is drawn to a method of inactivating a gene of interest, whereas group IV is drawn to activating a gene of interest. The two groups have opposite effects, resulting in the need for a separate examination. A search for one of these inventions would not necessarily return art against the other invention, due to the separate outcomes of each method. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group III is unrelated to the invention of group V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group III is drawn to a method of methylating a RASSF1 gene comprising exposing a cell to an siRNA which is specific

for a target sequence in a promoter region of the gene, whereas group V is drawn to a method of methylating an infectious agent gene or a viral infectious agent gene comprising exposing a cell to an siRNA which is specific for a target sequence in a coding region of the gene. Not only are the two groups targeted to separate and distinct genes, but they are also targeted to different regions on the gene of interest. Each of the different target genes, as well as regions within those genes, have separate nucleotide sequences containing no common core. The siNA molecules targeted to such sequences would each be separate and unique, resulting in the need for a separate examination. A search for one of these inventions would not necessarily return art against the other invention. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group III is unrelated to the invention of group VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group III is drawn to a method of methylating a RASSF1 gene comprising exposing a cell to an siRNA which is specific for a target sequence in a promoter region of the gene and inactivating the gene, whereas group VI is drawn to a method of methylating an infectious agent gene or a viral infectious agent gene comprising exposing a cell to an siRNA which is specific for a target sequence in a coding region of the gene and activating the gene. The two groups are targeted to separate and distinct genes, are targeted to different regions on the

genes, and have different effects. Each of the different target genes, as well as regions within those genes, have separate nucleotide sequences containing no common core. The siNA molecules targeted to such sequences would each be separate and unique, resulting in the need for a separate examination. Additionally, each of the groups have opposite outcomes, each requiring a separate examination. A search for one of these inventions would not necessarily return art against the other invention. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group III is unrelated to the invention of group VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group III is drawn to a method of methylating a gene comprising exposing a cell to an siRNA which is specific for a target sequence in a promoter region of the gene, whereas group VII is drawn to a method of methylating a gene comprising exposing a cell to an siRNA which is specific for a target sequence in a coding region of the gene. The sequence of the promoter region and the sequence of the coding region do not contain a common structural core. The siNA molecules targeted to such sequences would each be separate and unique. A search against one of the inventions would not necessarily return art for the other invention due to the separate and distinct target regions. A search for one of these inventions would

not necessarily return art against the other invention. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group III is unrelated to the invention of group VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group III is drawn to a method of methylating a gene comprising exposing a cell to an siRNA which is specific for a target sequence in a promoter region of the gene and inactivating a gene of interest, whereas group VIII is drawn to a method of methylating a gene comprising exposing a cell to an siRNA which is specific for a target sequence in a coding region of the gene and activating a gene of interest. The two groups have opposite effects, as well as targeting different regions. The sequence of the promoter region and the sequence of the coding region do not contain a common structural core. The siNA molecules targeted to such sequences would each be separate and unique, resulting in the need for a separate examination. A search for one of these inventions would not necessarily return art against the other invention. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group IV is unrelated to the invention of group V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as

capable of use together and have different effects. Group IV is drawn to a method of methylating a RASSF1 gene comprising exposing a cell to an siRNA which is specific for a target sequence in a promoter region of the gene and activating the gene, whereas group V is drawn to a method of methylating an infectious agent gene or a viral infectious agent gene comprising exposing a cell to an siRNA which is specific for a target sequence in a coding region of the gene and inactivating the gene. The two groups are targeted to separate and distinct genes, are targeted to different regions on the genes, and have different effects. Each of the different target genes, as well as regions within those genes, have separate nucleotide sequences containing no common core. The siRNA molecules targeted to such sequences would each be separate and unique, resulting in the need for a separate examination. Additionally, each of the groups have opposite outcomes, each requiring a separate examination. A search for one of these inventions would not necessarily return art against the other invention. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group IV is unrelated to the invention of group VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group IV is drawn to a method of methylating a RASSF1 gene comprising exposing a cell to an siRNA which is specific for a target sequence in a promoter region of the gene, whereas group VI is drawn to a

method of methylating an infectious agent gene or a viral infectious agent gene comprising exposing a cell to an siRNA which is specific for a target sequence in a coding region of the gene. Not only are the two groups targeted to separate and distinct genes, but they are also targeted to different regions on the gene of interest. Each of the different target genes, as well as regions within those genes, have separate nucleotide sequences containing no common core. The siNA molecules targeted to such sequences would each be separate and unique, resulting in the need for a separate examination. A search for one of these inventions would not necessarily return art against the other invention. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group IV is unrelated to the invention of group VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group IV is drawn to a method of methylating a gene comprising exposing a cell to an siRNA which is specific for a target sequence in a promoter region of the gene and activating a gene of interest, whereas group VII is drawn to a method of methylating a gene comprising exposing a cell to an siRNA which is specific for a target sequence in a coding region of the gene and inactivating a gene of interest. The two groups have opposite effects, as well as targeting different regions. The sequence of the promoter region and the sequence of the coding region do not contain a common structural core. The siNA molecules

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targeted to such sequences would each be separate and unique, resulting in the need for a separate examination. A search for one of these inventions would not necessarily return art against the other invention. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group IV is unrelated to the invention of group VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group IV is drawn to a method of methylating a gene comprising exposing a cell to an siRNA which is specific for a target sequence in a promoter region of the gene, whereas group VIII is drawn to a method of methylating a gene comprising exposing a cell to an siRNA which is specific for a target sequence in a coding region of the gene. The sequence of the promoter region and the sequence of the coding region do not contain a common structural core. The siRNA molecules targeted to such sequences would each be separate and unique. A search against one of the inventions would not necessarily return art for the other invention due to the separate and distinct target regions. A search for one of these inventions would not necessarily return art against the other invention. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group V is unrelated to the invention of group VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group V is drawn to a method of inactivating a gene of interest, whereas group VI is drawn to activating a gene of interest. The two groups have opposite effects, resulting in the need for a separate examination. A search for one of these inventions would not necessarily return art against the other invention, due to the separate outcomes of each method. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group V is unrelated to the invention of group VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group V is drawn to a method of methylating an infectious agent gene or a viral infectious agent gene, whereas group VII is drawn to a method of methylating a RASSF1 gene. Each of the different target genes have separate nucleotide sequences containing no common core. A search against one of the inventions would not necessarily return art for the other invention due to the separate and distinct target genes. A search for one of these inventions would not necessarily return art against the other invention, due to the difference in genes being targeted. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group V is unrelated to the invention of group VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group V is drawn to a method of methylating an infectious agent gene or a viral infectious agent gene comprising exposing a cell to an siRNA which is specific for a target sequence and inactivating the gene of interest, whereas group VIII is drawn to a method of methylating a RASSF1 gene comprising exposing a cell to an siRNA which is specific for a target sequence and activating the gene of interest. Not only are the two groups targeted to separate and distinct genes, but they also have opposite effects. Each of the different target genes have separate nucleotide sequences containing no common core. The siNA molecules targeted to such sequences would each be separate and unique, resulting in the need for a separate examination. A search for one of these inventions would not necessarily return art against the other invention. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group VI is unrelated to the invention of group VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group VI is drawn to a method of methylating an infectious agent gene or a viral infectious agent gene comprising

exposing a cell to an siRNA which is specific for a target sequence and activating the gene of interest, whereas group VII is drawn to a method of methylating a RASSF1 gene comprising exposing a cell to an siRNA which is specific for a target sequence and inactivating the gene of interest. Not only are the two groups targeted to separate and distinct genes, but they also have opposite effects. Each of the different target genes have separate nucleotide sequences containing no common core. The siRNA molecules targeted to such sequences would each be separate and unique, resulting in the need for a separate examination. A search for one of these inventions would not necessarily return art against the other invention. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group VI is unrelated to the invention of group VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group VI is drawn to a method of methylating an infectious agent gene or a viral infectious agent gene, whereas group VIII is drawn to a method of methylating a RASSF1 gene. Each of the different target genes have separate nucleotide sequences containing no common core. A search against one of the inventions would not necessarily return art for the other invention due to the separate and distinct target genes. A search for one of these inventions would not necessarily return art against the other invention, due to the difference in genes

being targeted. Therefore, to search more than one of these inventions in the same application presents a search burden.

The invention of group VII is unrelated to the invention of group VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and have different effects. Group VII is drawn to a method of inactivating a gene of interest, whereas group VIII is drawn to activating a gene of interest. The two groups have opposite effects, resulting in the need for a separate examination. A search for one of these inventions would not necessarily return art against the other invention, due to the separate outcomes of each method. Therefore, to search more than one of these inventions in the same application presents a search burden.

Because the inventions are distinct for the reasons given above, and because a search for art against one group would not necessarily return art against another, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755.

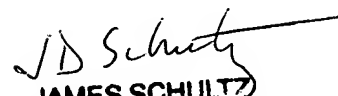
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Amy H. Bowman
Examiner
Art Unit 1635


JAMES SCHULTZ
PATENT EXAMINER